GP1656

#1/Election

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By: Leslie Lindsay
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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Bacher et al.	**Docket No.:**	16026/9267
Serial No.:	09/663,020	**Group Art Unit:**	1656
Filed:	September 15, 2000	**Examiner:**	S. Chunduru

FOR: DETECTION OF MICROSATELLITE INSTABILITY AND ITS USE IN DIAGNOSIS OF TUMORS

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In response to an Office Action mailed July 26, 2001, in which a restriction requirement was imposed, Applicants respectfully traverse the restriction requirement for the reasons set forth below.

Claims 1-47 are pending in the application. The Examiner required restriction to one of the following inventions: Group I (claims 1-34), drawn to methods of analyzing microsatellite loci; and Group II (claims 35-47), drawn to kits for analyzing microsatellite loci. In addition, the Examiner requires that Applicants elect a species for prosecution on the merits to which the claims shall be restricted if no generic claim is found to be allowable. The identified species include methods employing or kits containing nucleotide repeat loci selected from FGA, D1S518, D1S547, D1S1677, D2S1790, D3S2432, D5S818, D5S2849, D6S1053, D7S3046, D7S1808, D7S3070, D8S1179, D9S2169, D10S1426, D10S2470, D12S391, D17S1294, D17S1299, BAT-25, BAT-26, MONO-11, and MONO-15. Applicants elect Group I, claims 1-34, and species MONO-15 with traverse.

A proper requirement for restriction requires: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not imposed. The Examiner asserted that the inventions are distinct because the Group II and Group I claims are related as product and process of use claims. The related inventions are distinct if the process for using as claimed can be practiced with another materially different product, or the product can be used in a materially different process (MPEP 806.05(h)). The Examiner concluded that the claims are distinct because "the method of using the product in Group I can be used in a materially different processes such as hybridization assays or gene therapy assays."

Applicants respectfully submit that the claimed kits, which require oligonucleotide primers for co-amplifying a set of at least three microsatellite loci, the set comprising at least one mononucleotide repeat locus and at least two tetra-nucleotide repeat loci, could not be used in materially different processes, such as hybridization assays or gene therapy assays, as asserted by the Examiner. The direct hybridization assays suggested by the Examiner would not afford the requisite sensitivity for analyzing microsatellite loci. Applicants respectfully submit that the suggestion that primers for co-amplifying a set of at least three microsatellite loci of human genomic DNA, the set comprising at one mononucleotide repeat locus and two tetra-nucleotide repeat loci, could be used in gene therapy is not reasonable. Applicants are unable to identify any theory under which these primers could be used in gene therapy.

Applicants submit that restriction would not be appropriate in this case because examining the claims together would not impose a serious burden on the Patent Office. The MPEP provides that "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." (MPEP 803).

Applicants respectfully submit that all claims of the present application could be examined together without placing any serious burden on the Patent Office. The claims of Groups I and II are so inextricably related to one another that, for the sake of efficiency, all of the claims should be examined in a single application. All claims contain reference to a set of at least three microsatellite loci of human genomic DNA, the set comprising at one mononucleotide repeat locus and two tetra-nucleotide repeat loci. A complete search of the prior art relating to this common feature would necessarily require a search of the subject matter of both groups. Given the close relationship between the claims of Groups I and II, which the Examiner acknowledges are related, prosecution in the same application would be administratively efficient for the Patent Office.

The MPEP provides that "election of species should be required prior to a search on the merits (1) in all applications containing claims to a plurality of species with no generic claims, and (2) in all applications containing both species claims and generic or Markush claims." (MPEP 808.01(a)). Election of species is not be required in the present invention because the invention as claimed has generic claims, and does not have both species claims and generic claims. Furthermore, the present application does not recite such a multiplicity of species that an unduly extensive and burdensome search is required. Applicants respectfully request that the requirement to elect a species be withdrawn.

The one month period for responding to this Office Action fell on August 26, 2001, a Sunday. Because August 26, 2001 fell on a Saturday, the one month period for response expires today, August 27, 2001. No fee is believed due in connection with this response. However, if a fee is owed, please charge such fee to deposit account number 50-0842.

Applicants invite the Examiner to contact the undersigned should he require further clarification concerning this response.

Respectfully submitted,

Date: August 27, 2001

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